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Title: Preface and Table of Contents for Compendium of MCP Analytical Methods



The Compendium of Quality Assurance and Quality Control Requirements and Performance Standards for Selected Analytical Methods Used in Support of Response Actions for the Massachusetts Contingency Plan (MCP)

WSC - 02 - 320

#### <u>Preface</u>

This Compendium of Analytical Methods (CAM) provides (a) information and guidance to all parties on analytical and data quality issues, and (b) requirements and specifications for those parties who wish to obtain "Presumptive Certainty" for satisfying the data quality requirements of the MCP at 310 CMR 40.0017 and 310 CMR 40.0191(2)(c).

The information contained in this document is intended solely as guidance. This document does not create any substantive or procedural rights, and is not enforceable by any party in any administrative proceeding with the Commonwealth. The recommendations and guidance in this document provide approaches the Department considers acceptable for conditions and circumstances encountered at the majority of disposal sites to meet the performance standards set forth in sections 310 CMR 40.0017 and 310 CMR 40.0191(2)(c) of the MCP. Parties using this guidance should be aware that there may be other acceptable alternatives for achieving and documenting compliance with the general regulatory requirements and performance standards of the MCP, including those of sections 310 CMR 40.0017 and 310 CMR 40.0191. The regulatory citations in this document should not be relied upon as a complete list of the applicable regulatory requirements.

Consistent with the Commonwealth's e-Government initiative, the Compendium of Analytical Methods (CAM) is provided as an electronic document. This format enables electronic self-service and allows direct access by the Internet to the most recent revision of the individual analytical methods and guidelines that comprise this electronic compendium. This document is hosted on the Department of Environmental Protection's web site at <a href="http://www.ma.gov/dep/">http://www.ma.gov/dep/</a>.

It is anticipated that this document will be updated regularly by the Department to reflect changing technical standards, as well as analytical method modifications and additions. Therefore, the Department recommends that analytical methods and/or guidelines be accessed electronically and downloaded, as needed, rather than being kept "on the shelf" as a conventional reference document. This will allow users to ensure that the most recent revision of analytical methods and guidelines are utilized. All recent additions and revisions to this electronic document may be accessed by selecting the "Recent Additions" index tab on the data enhancement web page.

This document is available in alternative formats, if requested, by calling the Department's InfoLine at (617) 338-2255 or 1-800-462-0444 (Outside of Area Code 617)



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## WSC - CAM - I A

## Overview of the Analytical Data Enhancement Process For the Massachusetts Contingency Plan (MCP)

**Document Status:** Final

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## IA OVERVIEW OF THE MCP DATA ENHANCEMENT PROCESS

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#### 1.0 BACKGROUND

Pursuant to 310 CMR 40.0017, "any person undertaking response actions under the provisions of the MCP shall ensure that analytical and environmental monitoring data used in support of recommendations, conclusions, or Licensed Site Professional (LSP) opinions with respect to assessment, removal or containment actions are scientifically valid and defensible, and of a level of precision and accuracy commensurate with its stated or intended use."

An evaluation of the overall quality and suitability of data utilized to support site characterization decisions and opinions at a disposal site is the responsibility of parties conducting response actions, and is subject to the requirements of the Response Action Performance Standard (RAPS) set forth in 310 CMR 40.0191. Decisions that may directly impact data quality and suitability include:

- Selection of an analytical service provider;
- Identification of environmental sampling locations and parameters;
- > Identification of appropriate analytical methods and Reporting Limits; and
- Specification of Quality Assurance/Quality Control procedures and performance standards.

To address concerns that have arisen over site characterization efforts, and otherwise promote improved data quality, the Massachusetts Department of Environmental Protection (MADEP) has initiated an MCP Data Quality Enhancement Program using the successes of the Safe Drinking Water Act (SDWA) laboratory certification process and the recently promulgated VPH/EPH analytical and reporting approaches as models. The Program provides guidance and additional certainty for data users, regulators, and laboratories regarding the acceptability of analytical data used in support of MCP Response Actions.

Integral components of the program include:

- Education and training for LSPs and Department staff;
- Publication of a Compendium of Analytical Methods (CAM) detailing sampling and analytical guidelines that will enable parties to achieve "Presumptive Certainty" for the acceptability of data submissions; and
- Institution of a laboratory accreditation/certification process.

Specific Program elements are described in more detail in the following sections.



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## 2.0 Education and Training for LSPs and Department Staff

Education and training are two fundamental components of a comprehensive and effective analytical data quality assurance program. As a first step in the implementation of a comprehensive training program, the Department provided its own staff with data validation/data usability training. Consistent with agency goals, this fundamental training course was designed to provide a basic quality assessment "tool bundle" to appropriate staff. In addition, MADEP provided training during the second quarter of 2002 to both Department personnel and LSPs on the data enhancement process and the "Phase I MCP Analytical Methods" contained in the Compendium of Analytical Methods (CAM).

It is recognized that effective evaluation and review of environmental data requires the involvement of highly trained and experienced individuals accomplished in site assessment (where and how to collect a representative sample), analytical chemistry (measurement verification), and data interpretation (contaminant fate, transport and risk). The training provided by the Department to date has facilitated the development of these skills within both the agency and the regulated community.

## 3.0 COMPENDIUM OF ANALYTICAL METHODS (CAM)

#### 3.1 General

The Compendium of Analytical Methods (CAM) is a compilation of information on commonly used analytical protocols (e.g., EPA SW-846 Method 8260B). In addition to providing a succinct summary of each procedure, the CAM further articulates detailed quality control provisions and performance standards, analyte lists, reporting formats, appropriate sample containers, preservatives and analytical holding times; and other methodological elements – details that may not have been specified and/or are cited as discretionary in the original publications (e.g., EPA SW-846). Incorporation of the procedures and performance standards specified in the CAM into a cited method render that protocol an "MCP Analytical Method". MCP Analytical Methods are considered "methods published by the Department" pursuant to the provisions of 310 CMR 40.0017(2).

The CAM has two purposes and possible applications:

- ➤ In <u>all cases</u>, parties conducting response actions at MCP sites must <u>consider</u> the information and recommendations provided in CAM publications as *relevant guidance*, in accordance with the provisions of 310 CMR 40.0191(2)(a);
- ➤ <u>Electively</u>, parties conducting response actions at MCP sites <u>may choose to</u> conform to all specifications and requirements provided in the CAM publications for the "MCP Analytical Methods" along with any specified field collection and reporting procedures, to achieve "Presumptive Certainty" of data acceptance by agency reviewers.



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### 3.2 Presumptive Certainty

The term "Presumptive Certainty" as used in Sections I through VIII of the Compendium describes a particular status for analytical or environmental monitoring data used in support of MCP Response Action submittals. Obtaining "Presumptive Certainty" status is just one of a number of options available to satisfy the data quality requirements for MCP submittals described in 310 CMR 40.0017 and 40.0191. It should be clearly understood that exercising the "Presumptive Certainty" option is discretionary. However, parties who elect not to utilize the "Presumptive Certainty" option have an obligation, pursuant to 310 CMR 40.0017 and 40.0191(2)(c), to demonstrate and document an overall level of (laboratory and field) QA/QC, data usability, and data representativeness adequate for the intended use of the data.

In order to achieve "Presumptive Certainty", parties must:

- ✓ Use the "MCP Analytical Methods" detailed in the CAM;
- ✓ Comply with the applicable QC analytical requirements prescribed for the individual testing procedures in the CAM;
- ✓ Evaluate, and narrate, as necessary, compliance with performance standards described for the individual testing procedures in the CAM; and
- ✓ Adopt the reporting formats and elements specified in the CAM.

In achieving the status of "Presumptive Certainty", parties will be assured that an analytical data set<sup>1</sup>:

- ✓ Satisfy the broad <u>QA/QC requirements</u> of 310 CMR 40.0017 and 40.0191 regarding the scientific defensibility, precision and accuracy, and reporting of analytical data;
- ✓ May be used in a <u>data usability</u> assessment, and, if in compliance with all MCP
  Analytical Method standards, laboratory QC requirements, and field QC
  recommended limits and action levels, the data set will be considered usable
  data to support site characterization decisions made pursuant to the MCP; and
- ✓ May be used to support a data representativeness assessment.

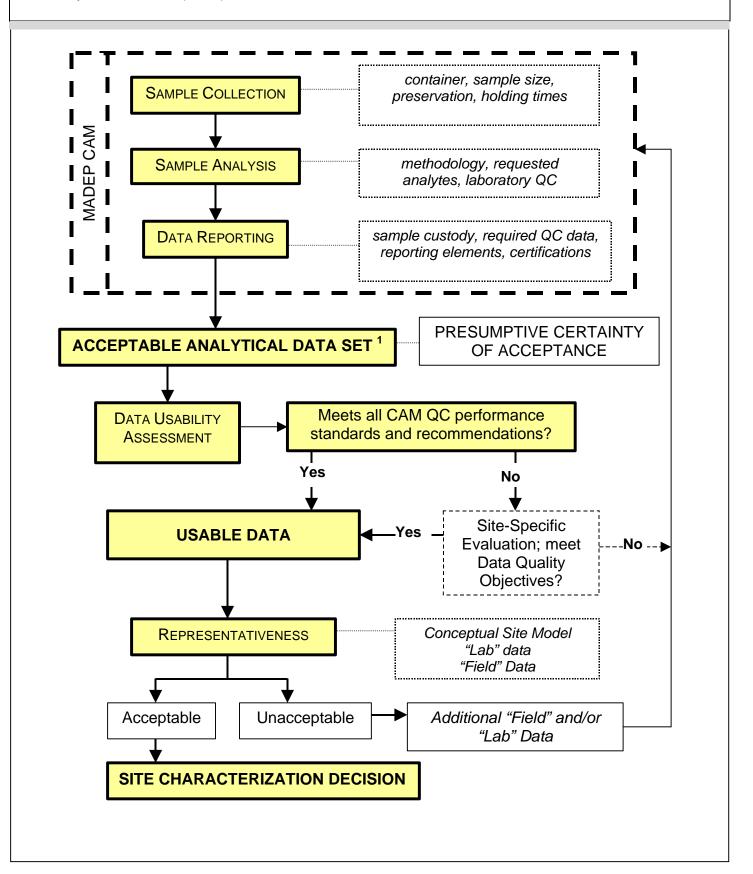
A logic diagram detailing the "Presumptive Certainty" approach is presented in Figure I A-1.

<sup>1.</sup> A group of samples collected, processed, and transported to a laboratory for analyses under similar conditions



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Figure 1A-1: Logic Diagram for Presumptive Certainty Concept for the MADEP Compendium of Analytical Methods (CAM)





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As indicated in Figure I A-1, use of the CAM and achievement of a "Presumptive Certainty" status will produce an analytical data set that will be accepted by agency reviewers for subsequent evaluation of data usability and representativeness.

It is stressed that "Presumptive Certainty" requirements are to be considered minimum requirements. Efforts that go beyond these minimum requirements (e.g., including additional analytes in a specific methodology) are considered compliant with the "Presumptive Certainty" concept and provisions, and need not be identified and discussed as an "exception".

#### 3.2.1 Data Usability

Data Usability refers to the extent to which a data set can adequately meet specific site characterization needs and data quality objectives. For example, are the Reporting Limits below applicable cleanup standards? Were all method QC measurements within specified limits; if not, can the data still be used to provide useful characterization information?

For parties who elect to follow the specifications in the CAM, data will be considered usable if all provisions and standards of the MCP Analytical Methods are met; including percent recovery limits for (any) method surrogate spikes and achievement of necessary (site-specific) Reporting Limits. It is expected that most analyses and analytical data sets will be within these specifications.

In cases where "Presumptive Certainty" is achieved but where data is qualified as being outside a required QC limit (e.g., low surrogate recoveries), additional evaluation, and possibly additional field sampling and analysis, may be necessary as part of and/or result of the data usability assessment. As stated in WSC-CAM VII A Section 2.2.1, "this document does not provide any specific guidance regarding proper sampling procedures, approaches to achieve representative sampling nor the type and frequency of field quality control samples required to evaluate overall data usability. Therefore, for example, before a low-recovery surrogate standard can be deemed a "matrix effect", it may be necessary to obtain and analyze a matrix spike sample.

It should be noted that proposed MCP regulatory changes ("Wave 2") will include a data usability assessment as a required component of the site assessment and/or closure (RAO) process. Detailed guidance regarding the required elements and performance standards for data usability assessments will be included in a separate policy effort.

#### 3.2.2 Data Representativeness

Data representativeness refers to the degree to which site information and data characterizes the types, locations, and concentrations of oil and hazardous materials at a disposal site. Such considerations should consider the totality of information available about a site via the Conceptual Site Model, "laboratory" data, and "field/ screening" data.



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The "Presumptive Certainty" concept and status articulated in the MCP CAM focuses primarily on the <u>quality</u> of site characterization data – not the <u>quantity</u> of site characterization data, which is often the more important of these two elements in a representativeness evaluation. Nonetheless, absent site-specific information on the likely presence of any given oil or hazardous material, parties who obtain "Presumptive Certainty" status and have adopted the method-specific analyte lists of the CAM can be assured of the acceptability of the *scope of testing* for each MCP Analytical Method for each *individual* environmental sample.

## 3.3 Laboratory Quality Control (QC)

The CAM provides the regulated community with a compilation of recommended laboratory procedures (MCP Analytical Methods) for the most common Contaminants of Concern (COCs) that may be used to support MCP Response Actions. These procedures, as described in Sections II through VIII of this Compendium, include detailed method-specific QA/QC requirements and performance standards for achievement of a "Presumptive Certainty" Status.

## 3.4 Field Quality Control (QC)

The level of field QC activities should be commensurate with: (a) the complexity of response actions conducted at a disposal site, (b) the potential risks posed to human health and the environment by the contaminants of concern, and (c) the intended use of the data. Data acquired from field QC procedures are used to:

- Estimate the overall quality (precision, accuracy and representativeness) of analytical data;
- Determine the need for actions to address problems or concerns over the quality of the data;
- ➤ Interpret results after actions are implemented to address problems or concerns over the quality of the data; and
- Demonstrate that remedial goals have been achieved.

A total program to produce data of suitable and acceptable quality should include both a Quality Assurance (QA) component, which encompasses the management procedures and controls as well as an operational Quality Control (QC) component, to assess the precision, accuracy (bias) and representativeness of the site data set. An effective program should identify and document data quality objectives to support the disposal site's response action requirements and establish sampling design criteria not only to acquire adequate site data but also to acquire the supporting data quality indicators. The disposal site assessment should include an evaluation of the data quality indicators associated with each site data set



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to determine if the pre-established data quality objectives for the disposal site assessment were achieved.

It should be noted that there are no prerequisites for obtaining "Presumptive Certainty" status with regard to the types and frequency of field QC data.

## 3.5 Reporting Content for Analytical and QC Data

The CAM describes in detail the reporting <u>content</u> for analytical and QC data for the MCP Analytical Methods but leave decisions regarding the reporting <u>format</u> of this information to the discretion of the analytical laboratory. The reporting content, specified in Section VIIA includes the following elements:

- Sample information (matrix, preservative, temperature on receipt, etc.);
- Analytical results (to include individual reporting limits for individual analytes, dilutions, extraction/pretreatment, etc.);
- QA/QC results (surrogate recovery, method blanks, etc., as applicable); and
- Laboratory analytical certification (method followed, acceptance criteria met, and documentation of method modifications or anomalies).

#### 3.6 Use of the Words "Shall" or "Must" in the CAM

The use of the words "**shall**" or "**must**" in the CAM is intended to identify specific tasks and/or activities that are necessary to satisfy the quality control requirements and performance standards of the individual MCP Analytical Methods in order to achieve "Presumptive Certainty" - *if a party elects to utilize the MCP Analytical Methods to satisfy the performance standards described in 310 CMR 40.0017 and 40.0191(2)(c).* 

The use of the words "shall" or "must" in the CAM in no way implies that the guidance provided is a mandatory regulatory requirement under M.G.L. c. 21E or the Massachusetts Contingency Plan (MCP).

#### 4.0 LABORATORY ACCREDITATION/CERTIFICATION

The Laboratory Certification Office (LCO), located at the MADEP Wall Experiment Station (WES), currently provides laboratory certification only for the chemical analysis of potable and non-potable water and microbiological analysis of potable water. The purpose of the Laboratory Certification Program is to identify laboratories in both the public and private sectors that are capable of consistently producing valid data. Towards this end, the LCO evaluates laboratories to ensure that they meet and continue to meet the performance and resource criteria set forth in 310 CMR 42.00 regarding laboratory personnel and



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qualifications, facilities, equipment, methodology employed, and quality assurance/quality control practices.

These reviews, which include annual proficiency tests and biennial on-site inspections, help ensure that the data produced by the laboratories are of known and documented quality, and suitable for their intended purpose. It should be clearly understood that certification alone can not guarantee the "validity" of the data produced by a laboratory.

A number of options to provide certification to laboratories that perform analyses of oil and hazardous materials (OHMs) and contaminated media in support of MCP response actions and other hazardous waste programs are currently under consideration by the Department.

#### 5.0 ALTERNATIVE APPROACHES

Consistent with the provisions of 310 CMR 40.0191, parties may continue to exercise professional judgment regarding the selection of alternative analytical approaches and methods. However, in all cases, sufficient documentation must be provided to support the decision that the selected analytical methods (and laboratory/field QA/QC procedures and results) meet the stated objectives of the plan for assessment of the disposal site, as well as the overall performance standards of 310 CMR 40.0017 and 40.0191(2)(c).